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June 11, 1999

BY HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
HFA-305, Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: Codex Alimentarius Commission, Committee on Nutrition and Foods for
Special Dietary Uses; Background Paper to Identify Perspectives and Issues
Pertaining to International Guidelines on Vitamin and Mineral Supplements,
64 Fed. Reg. 17397 (April 9, 1999), Docket No. 99 N-0391

Dear Sir or Madam:

On behalf of Starlight International, Ltd. (Starlight), Hyman, Phelps & McNamara, P.C. submits the following comments to the Food and Drug Administration (FDA) with respect to the above-referenced notice.

Starlight is a manufacturer and distributor of dietary supplements in the United States and plans to market its products internationally in the future. Starlight is generally interested in the standard-setting activities of the Codex Alimentarius Commission (Codex) and is particularly interested in the work of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in attempting to establish guidelines for vitamin and mineral supplements for the purposes of international trade.

99N-0391

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As stated in comments previously filed to FDA on January 28, 1998 concerning Proposed Draft Guidelines for Vitamin and Mineral Supplements under consideration by the CCNFSDU, Starlight is opposed to the development of Codex guidelines for supplement-type products. The CCNFSDU's work is a component of the sanitary and phytosanitary standard-setting activities of the Codex, and, therefore, any guidelines established by the CCNFSDU must be based on sound scientific principles in accordance with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), concluded as part of the Uruguay Round of Multilateral Trade Negotiations.¹ No viable scientific approach exists, however, for establishing a world-wide standard relating to the composition and potency of supplement-type products. Moreover, given the extreme variations in regional, national and individual diets, it is not possible to establish universal compositional limits for vitamin and mineral supplements according to sound scientific methodology. Starlight's comments focus on this fundamental issue.

Starlight acknowledges the CCNFSDU's decision to retain the Proposed Draft Guidelines for Vitamin and Mineral Supplements at Step 4, while attempting to create a common framework for discussion through the development of a "background paper," as a positive development in the Codex decision-making process. At the same time, Starlight believes that the forthcoming "background paper" will not facilitate the work of the CCNFSDU in establishing such guidelines. To the contrary, Starlight expects that a thorough examination of the issues associated with the international use and legal classification of supplement-type products will show that no reasonable basis exists to support the development of world-wide standards limiting the composition and potency of dietary supplements.

Starlight believes that, as a preliminary matter, the background paper should consider whether it is appropriate for the CCNFSDU to continue attempting to develop international guidelines for vitamin and mineral supplements, since it is not possible to establish science-based standards limiting the composition and potency of supplement-type products. To illustrate, one of several alternatives for establishing maximum upper limits for nutrients in vitamin and mineral supplements in the Proposed Draft Guidelines is based on purportedly "scientific" risk assessment methodology. Under this approach, supplements may contain vitamins and minerals up to a level that is considered safe on the

¹ Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 33 I.L.M. 1, Agreement on the Application of Sanitary and Phytosanitary Measures, II Annex 1A4, April 15, 1994.

basis of risk assessment considerations, as determined by appropriate risk assessment methodology, taking into account all sources of nutrients in the diet.²

According to this approach, maximum safe levels for nutrients may be determined by identifying the highest intake levels not associated with adverse effects and the lowest intake levels associated with adverse effects and calculating a safe range. This method presumes, however, that "all sources of nutrients in the diet" can be factored into the analysis, which is clearly not possible. Since there is no single world diet to produce comparable and predictable nutrient consumption patterns, it is not possible to calculate safe upper limits of nutrients based on "all sources of nutrients in the diet." Moreover, international differences in diet are so great that it is impossible to even extrapolate a range in nutrient consumption upon which to base such risk assessment methodology.

Other aspects of a world-wide standard for supplement-type products are equally unsupportable. It is arbitrary to attempt to create standards for supplement-type products moving in international commerce that would restrict the composition of such products to include solely vitamins and minerals whose indispensability for humans has been proven by scientific data, and exclude other substances that are widely used in many parts of the world as "dietary" substances, such as herbs and other botanicals. The health-related benefits provided by many substances that have not been identified as "indispensable" for human growth, such as antioxidants, for example, is now well-established. Any attempt to preclude such safe and useful substances from inclusion in supplement-type products has no rational scientific basis.

Furthermore, particularly in light of increasing consumer awareness and demand for unrestricted access to safe and useful supplement-type products and the diverse regulatory philosophies that exist throughout the world concerning the legal classification of a product as a "food" or a "drug," it is not feasible to establish a uniform global standard for such products under the guise of protecting the public health and safety. Moreover, such standards would actually act to restrict international free trade of safe and useful supplement-type products.

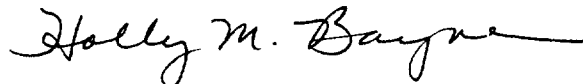
² Codex Alimentarius Commission, Proposed Draft Guidelines for Vitamin and Mineral Supplements, ALINORM 95/26, Appendix VI (emphasis added).

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Starlight urges FDA to continue to oppose the development of Codex guidelines for supplement-type products and to ensure that the background paper addresses the fact that no rational scientific basis exists to support world-wide standards for supplement-type products.

Sincerely,

A handwritten signature in cursive script that reads "Holly M. Bayne". The signature is fluid and extends to the right.

A. Wes Siegner, Jr.

Holly M. Bayne

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